UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

UNITED STATES OF AMERICA, *ex rel.* JON VITALE, Plaintiff, v. MIMEDX GROUP, INC. Defendant.	Civil Action No. 3:17-cv-00166-RBH **MIMEDX GROUP, INC.'S RESPONSE TO THE UNITED STATES' STATEMENT OF INTEREST**

MiMedx Group, Inc. ("MiMedx") submits this response to the United States' Statement of Interest (Dkt. 68) ("SOI") filed on November 6, 2018.

The primary argument advanced in the SOI is that manufacturer donations to third-party patient assistance programs ("PAPs") may, under certain circumstances, violate the AKS. MiMedx has never argued otherwise. Rather, MiMedx contends that the Relator in *this case* has failed to plead facts with the particularity required by Rule 9(b) to support an inference that MiMedx's charitable donations to PAN constitute unlawful remuneration under the AKS. Nothing in the government's SOI provides a basis to conclude otherwise. Indeed, the government expressly takes no position regarding MiMedx's argument that the Complaint fails to plead Relator's claims with particularity as required by Rule 9(b) or MiMedx's motion under the FCA's public disclosure bar. SOI at 1-2.

I. Relator Has Not Adequately Pleaded an AKS Claim.

As an initial matter, it is worth noting that the applicable OIG guidance that applies to the arrangement between MiMedx and the PAN Foundation at issue in this case expressly

acknowledges the appropriateness of PAPs that provide copayment assistance for Medicare beneficiaries under the circumstances described in the guidance. Dkt. 65-1 at 8-12.

The government's only reference to the guidance is to portions that are inapplicable to the facts of this case. The guidance discusses two distinct types of PAPs – Pharmaceutical Manufacturer PAPs, *i.e.*, PAPs operated by manufacturers; and Independent Charity PAPs, *i.e.*, PAPs operated by independent charities. The PAN Foundation is not (and is not alleged to be) a Pharmaceutical Manufacturer PAP. Nor is PAN affiliated with MiMedx (or alleged to be). Rather, PAN is an Independent Charity PAP. Compl. ¶ 104. Yet the government's only citations to the OIG guidance are to portions that discuss concerns about Pharmaceutical Manufacturer PAPs. SOI at 4 (citing to 70 Fed. Reg. 70623, 70625); *id.* at 6-7 (mis-citing the same provision). However, the difference between the two types of PAPs is of great significance to the AKS analysis, as set forth in the guidance. While OIG takes the position that "pharmaceutical manufacturer PAPs that subsidize Part D cost-sharing amounts present heightened risks under the anti-kickback statute," it concludes that "cost-sharing subsidies provided by *bona fide*, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, even if the charities receive manufacturer contributions." *Id.* at 70624; *see also id.* at 70625 ("[C]ost-sharing subsidies provided by pharmaceutical manufacturer PAPs pose a heightened risk of fraud under the Federal anti-kickback statute. However, there are non-abusive alternatives available. In particular, as discussed below, pharmaceutical manufacturers can donate to *bona fide* independent charity PAPs, provided appropriate safeguards exist.").

Rather than addressing the specific OIG guidance relating to Independent Charity PAPs, the government asserts that MiMedx "seems to suggest that HHS-OIG is unconcerned with the

AKS implications of" PAPs "so long as the payment is through an intermediary foundation." SOI at 6. MiMedx, however, has made no such argument. Rather, MiMedx contends that the guidance reflects that manufacturer donations to independent charities are not inherently pernicious, and Relator fails to allege specific facts that would raise concerns under the AKS based on the specific factors identified by OIG.

The government also asserts that the Advisory Opinion that OIG provided to PAN is not dispositive of MiMedx's potential AKS liability. Again, MiMedx has not argued otherwise.[1] But while the Advisory Opinion is not dispositive, it is judicially-noticeable authority supporting MiMedx's argument that the Complaint fails to plead that the arrangement between MiMedx and PAN constitutes unlawful remuneration. Dkt. 65-2 at 9 ("[T]here would appear to be a minimal risk that donor contributions would improperly influence referrals by the Foundation."); *id.* at 12 ("Donors have no assurance that the amount of financial assistance their patients, clients, or customers receive bears any relationships to the amount of their donations. Indeed, donors are not guaranteed that any of their patients, clients, or customers receives any financial assistance whatsoever from the Foundation. In these circumstances, we do not believe that the contributions made by donors to the Foundation can reasonably be construed as payments to eligible beneficiaries of the Medicare or Medicaid programs or to the Foundation to arrange for referrals."). In light of the Advisory Opinion and the guidance, Relator does not adequately plead how MiMedx violated the AKS.

The government also emphasizes that indirect remuneration can be just as unlawful under the AKS as direct remuneration. SOI at 6. Again, MiMedx takes no issue with this general proposition. But OIG, which is legally responsible for issuing guidance on compliance with the

[1] Nor has MiMedx argued that "one must plead that there was non-compliance with the advisory opinion to allege an AKS violation," as the government suggests. SOI at 8.

AKS, has concluded that "[u]nder a properly structured program," PAPs operated by independent charities "should raise few, if any concerns" under the AKS. Dkt. 65-2 at 9.[2] The guidance identifies specific factors and guidance relating to the "nature, structure, sponsorship, and funding" of such PAPs. *Id.* What MiMedx argued, and what the SOI does not address, is that the allegations *in this case* fail to adequately plead that MiMedx's charitable donations to the PAN Foundation constitute unlawful remuneration under the AKS.

In sum, the thrust of the government's argument appears to be that neither the PAN Advisory Opinion nor the OIG guidance is necessarily *dispositive* of MiMedx's AKS liability. MiMedx does not dispute this. But there still must be *some* well-pleaded factual basis to support an allegation that a manufacturer who contributes to an Independent Charity PAP that complies with the OIG guidance constitutes an illegal kickback scheme that renders the manufacturer liable under the AKS. Indeed, the logical implication of the government's position is that even though it is legal for an appropriately-structured PAP to provide charitable assistance to Medicare beneficiaries, it is nonetheless illegal for a manufacturer to donate to that PAP if the manufacturer desires to help patients who suffer from a condition that the manufacturer's products treat. But that conclusion would be inconsistent with the OIG guidance, and would subject any manufacturer to expensive and time-consuming discovery and the threat of ruinous FCA liability based on nothing more than the allegation that the manufacturer understood that funds that it donated could potentially be used to facilitate use of the manufacturer's product.

[2] In advancing this argument, the government again cites to the portion of the OIG guidance that discusses concerns that arise regarding Pharmaceutical Manufacturer PAPs (as distinct from Independent Charity PAPs) which, as noted above, is inapplicable here. SOI at 6-7.

II. Relator Has Not Adequately Pleaded Causation.

The crux of the government's argument regarding causation relies on a misunderstanding of MiMedx's position. At no point has MiMedx asserted that Relator must prove that "federal beneficiaries would not have purchased MiMedx products *but for* the alleged kickback." SOI at 4 (emphasis in original). Rather, MiMedx's argument with respect to Relator's PAN allegations is that "Relator fails to plead any facts linking MiMedx's donations with any specific PAN charitable award and subsequent claim for payment." Dkt. 65-2 at 14-15. As MiMedx explained in its Motion, the Fourth Circuit has made clear that "allegations of a fraudulent scheme" are insufficient to state a claim under the FCA "in the absence of an assertion that a specific false claim was presented to the government for payment." *U.S. ex rel. Nathan v. Takeda Pharm. N. Am., Inc.*, 707 F.3d 451, 456 (4th Cir. 2013). Therefore, under well-established Fourth Circuit authority, Relator fails to state a claim for a violation of the FCA in the absence of a specific false claim submitted as a result of MiMedx's alleged AKS violation.

The SOI glosses over controlling Fourth Circuit authority, and instead, advocates adherence to other cases, in particular the Third Circuit's opinion in *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 95 (3d Cir. 2018). The issue in that case was "what 'link' is sufficient to connect an alleged kickback scheme to a subsequent claim for reimbursement: a direct causal link, no link at all, or something in between." *Id*. at 95. The court disagreed with defendant's position that the link should be but-for causation, and instead held that Relator had to prove that "at least one of [defendant's] claims sought reimbursement for medical care that was provided in violation of the Anti–Kickback Statute." *Id*. at 98. This case has no bearing on the causation issue presented by MiMedx's motion.

For the foregoing reasons and those set forth in the prior briefs, MiMedx submits that Relator's complaint should be dismissed with prejudice.

Respectfully submitted,

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